

108TH CONGRESS  
1ST SESSION

# S. 1225

Entitled the “Greater Access to Affordable Pharmaceuticals Act”.

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IN THE SENATE OF THE UNITED STATES

JUNE 10, 2003

Mr. GREGG (for himself, Mr. SCHUMER, Mr. MCCAIN, and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

Entitled the “Greater Access to Affordable Pharmaceuticals Act”.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Greater Access to Af-  
5       fordable Pharmaceuticals Act”.

6       **SEC. 2. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

7       (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-  
8       tion 505(j) of the Federal Food, Drug, and Cosmetic Act  
9       (21 U.S.C. 355(j)) is amended—

1           (1) in paragraph (2)(A)(vii), by inserting after  
 2           “each patent” the following: “published by the Sec-  
 3           retary under subsection (b)(1) or (c)(2) at least 1  
 4           day before the date on which the application is  
 5           filed”; and

6           (2) in paragraph (5)—

7                 (A) in subparagraph (B)(iii)—

8                         (i) by striking “paragraph (2)(B)(i)”  
 9                         each place it appears and inserting “para-  
 10                         graph (2)(B)”;

11                        (ii) in the first sentence, by inserting  
 12                        after “of a patent” the following: “pub-  
 13                        lished by the Secretary under subsection  
 14                        (b)(1) or (c)(2) at least 1 day before the  
 15                        date on which the application is filed”; and

16                        (iii) in subclauses (I), (II), and (III)  
 17                        of the second sentence, by striking “the  
 18                        court” and inserting “the United States  
 19                        district court presiding over the matter”;

20                 (B) by redesignating subparagraphs (C)  
 21                 and (D) as subparagraphs (E) and (F), respec-  
 22                 tively; and

23                 (C) by inserting after subparagraph (B)  
 24                 the following:

1                   “(C) AVAILABILITY OF 30-MONTH PE-  
2                   RIOD.—

3                   “(i) IN GENERAL.—The 30-month pe-  
4                   riod provided under subparagraph (B)(iii)  
5                   shall be available only with respect to a  
6                   patent published by the Secretary under  
7                   subsection (b)(1) or (c)(2) at least 1 day  
8                   before the date on which the application is  
9                   filed.

10                  “(ii) SUBSEQUENTLY PUBLISHED  
11                  PATENTS.—

12                  “(I) IN GENERAL.—If a patent is  
13                  published by the Secretary under sub-  
14                  section (b)(1) or (c)(2) subsequent to  
15                  the filing of an application described  
16                  in paragraph (2)(A) but before ap-  
17                  proval of that application (referred to  
18                  in this clause as a ‘subsequently pub-  
19                  lished patent’), and the patent claims  
20                  the listed drug referred to in para-  
21                  graph (2)(A)(i) or a use for the listed  
22                  drug for which the applicant is seek-  
23                  ing approval under this subsection  
24                  and for which information is required  
25                  to be filed under subsection (b) or (c),

1 the applicant shall amend the applica-  
2 tion to include a certification de-  
3 scribed in paragraph (2)(A)(vii) or a  
4 statement described in paragraph  
5 (2)(A)(viii) for the patent.

6 “(II) NO ADDITIONAL 30-MONTH  
7 PERIOD.—The 30-month period de-  
8 scribed in subparagraph (B)(iii) shall  
9 not be available with respect to a cer-  
10 tification described in paragraph  
11 (2)(A)(vii)(IV) when the subject of  
12 that certification is a subsequently  
13 published patent.

14 “(III) CHALLENGE TO SUBSE-  
15 QUENTLY PUBLISHED PATENT IN SEP-  
16 ARATE PROCEEDING.—If the same ap-  
17 plicant makes a certification described  
18 in paragraph (2)(A)(vii)(IV) with re-  
19 spect to the subsequently published  
20 patent in a separate application under  
21 this subsection, the 30-month period  
22 provided under subparagraph (B)(iii)  
23 shall be available in connection with  
24 the separate application.

1 “(iii) CIVIL ACTION TO OBTAIN PAT-  
2 ENT CERTAINTY.—

3 “(I) DECLARATORY JUDGMENT  
4 ABSENT INFRINGEMENT ACTION.—If  
5 the owner of a patent fails to bring a  
6 civil action against the applicant for  
7 infringement of the patent on or be-  
8 fore the date that is 45 days after the  
9 date on which the notice provided  
10 under paragraph (2)(B) was received,  
11 the applicant may bring a civil action  
12 against the owner of the patent for a  
13 declaratory judgment under section  
14 2201 of title 28, United States Code,  
15 that the patent is invalid, is unen-  
16 forceable, or will not otherwise be in-  
17 fringed by the new drug for which the  
18 person seeks approval.

19 “(II) COUNTERCLAIM TO IN-  
20 FRINGEMENT ACTION.—

21 “(aa) IN GENERAL.—If the  
22 owner of the patent brings a pat-  
23 ent infringement action against  
24 the applicant, the applicant may  
25 assert a counterclaim seeking an

1 order requiring the patent owner  
 2 to correct or delete patent infor-  
 3 mation filed by the patent owner  
 4 under subsection (b) or (c) on  
 5 the ground that the patent does  
 6 not claim—

7 “(AA) the drug for  
 8 which the application was  
 9 approved; or

10 “(BB) an approved  
 11 method of using the drug.

12 “(bb) NO DAMAGES.—An  
 13 applicant shall not be entitled to  
 14 damages on a counterclaim under  
 15 item (aa).

16 “(cc) NO INDEPENDENT  
 17 CAUSE OF ACTION.—Item (aa)  
 18 does not authorize the assertion  
 19 of a claim described in item (aa)  
 20 in any civil action or proceeding  
 21 other than a counterclaim de-  
 22 scribed in item (aa).”.

23 (b) APPLICATIONS GENERALLY.—Section 505 of the  
 24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)  
 25 is amended—

1 (1) in subsection (b)(2)(A), by inserting after  
 2 “each patent” the following: “published by the Sec-  
 3 retary under paragraph (1) or subsection (c)(2) at  
 4 least 1 day before the date on which the application  
 5 is filed”; and

6 (2) in subsection (c)—

7 (A) in paragraph (3)(C)—

8 (i) by striking “paragraph (3)(B)”  
 9 each place it appears and inserting “para-  
 10 graph (3)”;

11 (ii) in the first sentence, by inserting  
 12 after “of a patent” the following: “pub-  
 13 lished by the Secretary under paragraph  
 14 (2) or subsection (b)(1) at least 1 day be-  
 15 fore the date on which the application is  
 16 filed”; and

17 (iii) in clauses (i), (ii), and (iii) of the  
 18 second sentence, by striking “the court”  
 19 and inserting “the United States district  
 20 court presiding over the matter”;

21 (B) by redesignating paragraph (4) as  
 22 paragraph (5); and

23 (C) by inserting after paragraph (3) the  
 24 following:

25 “(4) AVAILABILITY OF 30-MONTH PERIOD.—

“(A) IN GENERAL.—The 30-month period provided under paragraph (3)(C) shall be available only with respect to a patent published by the Secretary under paragraph (2) or subsection (b)(1) at least 1 day before the date on which the application is filed.

“(B) SUBSEQUENTLY PUBLISHED PATENTS.—

“(i) IN GENERAL.—If a patent is published by the Secretary under paragraph (2) or subsection (b)(1) subsequent to the filing of an application described in subsection (b)(2) but before approval of that application (referred to in this subparagraph as a ‘subsequently published patent’), and the patent claims the listed drug or a use for the listed drug for which the applicant is seeking approval, the applicant shall amend the application to include a certification described in subsection (b)(2)(A) or a statement described in subsection (b)(2)(B) for the patent.

“(ii) NO ADDITIONAL 30-MONTH PERIOD.—The 30-month period described in paragraph (3)(C) shall not be available

1 with respect to a certification described in  
2 subsection (b)(2)(A)(iv) when the subject  
3 of that certification is a subsequently pub-  
4 lished patent.

5 “(iii) CHALLENGE TO SUBSEQUENTLY  
6 PUBLISHED PATENT IN SEPARATE PRO-  
7 CEEDING.—If the same applicant makes a  
8 certification described in subsection  
9 (b)(2)(A)(iv) with respect to the subse-  
10 quently published patent in a separate ap-  
11 plication under this subsection, the 30-  
12 month period provided under paragraph  
13 (3)(C) shall be available in connection with  
14 the separate application.

15 “(C) CIVIL ACTION TO OBTAIN PATENT  
16 CERTAINTY.—

17 “(i) DECLARATORY JUDGMENT AB-  
18 SENT INFRINGEMENT ACTION.—If the  
19 owner of a patent fails to bring a civil ac-  
20 tion against the applicant for infringement  
21 of the patent on or before the date that is  
22 45 days after the date on which the notice  
23 provided under paragraph (2)(B) was re-  
24 ceived, the applicant may bring a civil ac-  
25 tion against the owner of the patent for a

1 declaratory judgment under section 2201  
2 of title 28, United States Code, that the  
3 patent is invalid, is unenforceable, or will  
4 not otherwise be infringed by the new drug  
5 for which the person seeks approval.

6 “(ii) COUNTERCLAIM TO INFRINGE-  
7 MENT ACTION.—

8 “(I) IN GENERAL.—If the owner  
9 of the patent brings a patent infringe-  
10 ment action against the applicant, the  
11 applicant may assert a counterclaim  
12 seeking an order requiring the patent  
13 owner to correct or delete patent in-  
14 formation filed by the patent owner  
15 under subsection (b) or (c) on the  
16 ground that the patent either does not  
17 claim the drug for which the applica-  
18 tion was approved or does not claim—

19 “(aa) the drug for which the  
20 application was approved; or

21 “(bb) an approved method  
22 of using the drug.

23 “(II) NO DAMAGES.—An appli-  
24 cant shall not be entitled to damages  
25 on a counterclaim under subclause (I).

1 “(III) NO INDEPENDENT CAUSE  
2 OF ACTION.—Subclause (I) does not  
3 authorize the assertion of a claim de-  
4 scribed in subclause (I) in any civil  
5 action or proceeding other than a  
6 counterclaim described in subclause  
7 (I).”.

8 (c) INFRINGEMENT ACTIONS.—Section 271(e) of title  
9 35, United States Code, is amended by adding at the end  
10 the following:

11 “(5) CASE OR CONTROVERSY.—The filing of an  
12 application described in paragraph (2) that includes  
13 a certification under subsection (b)(2)(A)(iv) or  
14 (j)(2)(A)(vii)(IV) of section 505 of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C. 355), and  
16 the failure of the owner of the patent to bring an  
17 action for infringement of a patent that is the sub-  
18 ject of the certification before the expiration of 45  
19 days after the date on which the notice provided  
20 under subsection (b)(3) or (j)(2)(B) of that section  
21 is received, shall establish an actual controversy be-  
22 tween the applicant and the patent owner sufficient  
23 to confer subject matter jurisdiction in the courts of  
24 the United States for any action brought by the ap-  
25 plicant under section 2201 of title 28 for a declara-

1 tory judgment that any patent that is the subject of  
 2 the certification is invalid, unenforceable, or not in-  
 3 fringed.”.

4 (d) **EFFECTIVE DATE.**—The amendments made by  
 5 subsections (a) and (b) shall be effective with respect to  
 6 any certification under subsection (b)(2)(A)(iv) or  
 7 (j)(2)(A)(vii)(IV) of section 505 of the Federal Food,  
 8 Drug, and Cosmetic Act (21 U.S.C. 355) made after the  
 9 date of enactment of this Act in an application filed under  
 10 subsection (b)(2) or (j) of that section or in an amendment  
 11 to an application filed under subsection (b)(2) or (j) of  
 12 that section.

13 **SEC. 3. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

14 (a) **IN GENERAL.**—Section 505(j)(5) of the Federal  
 15 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as  
 16 amended by section 2) is amended—

17 (1) in subparagraph (B)(iv), by striking sub-  
 18 clause (II) and inserting the following:

19 “(II) the earlier of—

20 “(aa) the date of a final de-  
 21 cision of a court from which no  
 22 appeal has or can be taken other  
 23 than a petition to the Supreme  
 24 Court for a writ of certiorari  
 25 holding that the patent that is

1 the subject of the certification is  
 2 invalid or not infringed; or

3 “(bb) the date of a settle-  
 4 ment order or consent decree  
 5 signed by a Federal judge that  
 6 enters a final judgment and in-  
 7 cludes a finding that the patent  
 8 that is the subject of the certifi-  
 9 cation is invalid or not otherwise  
 10 infringed;”; and

11 (2) by inserting after subparagraph (C) the fol-  
 12 lowing:

13 “(D) FORFEITURE OF 180-DAY EXCLU-  
 14 SIVITY PERIOD.—

15 “(i) DEFINITION OF FORFEITURE  
 16 EVENT.—In this subparagraph, the term  
 17 ‘forfeiture event’, with respect to an appli-  
 18 cation under this subsection, means the oc-  
 19 currence of any of the following:

20 “(I) FAILURE TO MARKET.—The  
 21 applicant fails to market the drug by  
 22 the later of—

23 “(aa) the date that is 60  
 24 days after the date on which the  
 25 approval of the application for

1 the drug is made effective under  
2 subparagraph (B)(iii); or

3 “(bb) if 1 or more civil ac-  
4 tions have been brought against  
5 the applicant for infringement of  
6 a patent subject to a certification  
7 under paragraph (2)(A)(vii)(IV)  
8 or 1 or more civil actions have  
9 been brought by the applicant for  
10 a declaratory judgment that such  
11 a patent is invalid or not other-  
12 wise infringed, the date that is  
13 60 days after the date of a final  
14 decision of a court from which no  
15 appeal has been or can be taken  
16 (other than a petition to the Su-  
17 preme Court for a writ of certio-  
18 rari) in the last of those civil ac-  
19 tions to be decided.

20 “(II) WITHDRAWAL OF APPLICA-  
21 TION.—The applicant withdraws the  
22 application.

23 “(III) AMENDMENT OF CERTIFI-  
24 CATION.—The applicant amends the  
25 certification from a certification under

1 paragraph (2)(A)(vii)(IV) to a certifi-  
2 cation under paragraph  
3 (2)(A)(vii)(III).

4 “(IV) FAILURE TO OBTAIN TEN-  
5 TATIVE APPROVAL.—The applicant  
6 fails to obtain tentative approval of an  
7 application within 30 months after the  
8 date on which the application is filed,  
9 unless the failure is caused by a  
10 change in the requirements for ap-  
11 proval of the application imposed after  
12 the date on which the application is  
13 filed.

14 “(V) FAILURE TO CHALLENGE  
15 PATENT.—In a case in which, after  
16 the date on which the applicant sub-  
17 mitted the application, new patent in-  
18 formation is submitted under sub-  
19 section (c)(2) for the listed drug for a  
20 patent for which certification is re-  
21 quired under paragraph (2)(A), the  
22 applicant fails to submit, not later  
23 than the date that is 60 days after the  
24 date on which the Secretary publishes

1 the new patent information under  
2 paragraph (7)(A)(iii)—

3 “(aa) a certification de-  
4 scribed in paragraph  
5 (2)(A)(vii)(IV) with respect to  
6 the patent to which the new pat-  
7 ent information relates; or

8 “(bb) a statement that any  
9 method of use claim of that pat-  
10 ent does not claim a use for  
11 which the applicant is seeking  
12 approval under this subsection in  
13 accordance with paragraph  
14 (2)(A)(viii).

15 “(VI) AGREEMENT WITH PATENT  
16 OWNER.—The applicant enters into  
17 an agreement with the owner of the  
18 patent—

19 “(aa) that is the subject of  
20 the certification under paragraph  
21 (2)(A)(vii)(IV); and

22 “(bb) that the Federal  
23 Trade Commission determines  
24 has violated the antitrust laws  
25 (as defined in section 1 of the

1 Clayton Act (15 U.S.C. 12), ex-  
2 cept that the term includes sec-  
3 tion 5 of the Federal Trade Com-  
4 mission Act (15 U.S.C. 45) to  
5 the extent that that section ap-  
6 plies to unfair methods of com-  
7 petition).

8 “(ii) FORFEITURE.—The 180-day ex-  
9 clusivity period described in subparagraph  
10 (B)(iv) shall be forfeited by an applicant if  
11 a forfeiture event occurs.

12 “(iii) SUBSEQUENT APPLICANT.—If  
13 an applicant forfeits the 180-day exclu-  
14 sivity period under clause (ii)—

15 “(I) a subsequent application  
16 containing a certification described in  
17 paragraph (2)(A)(vii)(IV) shall be-  
18 come effective immediately on ap-  
19 proval; and

20 “(II) the subsequent applicant  
21 shall not be eligible for a 180-day ex-  
22 clusivity period under subparagraph  
23 (B)(iv).

24 “(E) AVAILABILITY.—The 180-day period  
25 under subparagraph (B)(iv) shall be available to

1           a first applicant submitting an application for a  
2           drug with respect to any patent without regard  
3           to whether an application has been submitted  
4           for the drug under this subsection containing  
5           such a certification with respect to a different  
6           patent.”.

7           (b) **APPLICABILITY.**—The amendment made by sub-  
8   section (a) shall be effective only with respect to an appli-  
9   cation filed under section 505(j) of the Federal Food,  
10  Drug, and Cosmetic Act (21 U.S.C. 355 (j)) after the date  
11  of enactment of this Act for a listed drug for which no  
12  certification under section 505(j)(2)(A)(vii)(IV) of that  
13  Act was made before the date of enactment of this Act,  
14  except that if a forfeiture event described in section  
15  505(j)(5)(D)(i)(VI) of that Act occurs in the case of an  
16  applicant, the applicant shall forfeit the 180-day period  
17  under section 505(j)(5)(B)(iv) of that Act without regard  
18  to when the applicant made a certification under section  
19  505(j)(2)(A)(vii)(IV).

20   **SEC. 4. BIOAVAILABILITY AND BIOEQUIVALENCE.**

21           (a) **IN GENERAL.**—Section 505(j)(8) of the Federal  
22  Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is  
23  amended—

24                   (1) by striking subparagraph (A) and inserting  
25           the following:

1           “(A)(i) The term ‘bioavailability’ means the  
2           rate and extent to which the active ingredient or  
3           therapeutic ingredient is absorbed from a drug and  
4           becomes available at the site of drug action.

5           “(ii) For a drug that is not intended to be ab-  
6           sorbed into the bloodstream, the Secretary may as-  
7           sess bioavailability by scientifically valid measure-  
8           ments intended to reflect the rate and extent and ex-  
9           tent to which the active ingredient or active moiety  
10          becomes available at the site of drug action.”; and

11          (2) by adding at the end the following:

12          “(C) For a drug that is not intended to be ab-  
13          sorbed into the bloodstream, the Secretary may es-  
14          tablish alternative, scientifically valid methods to  
15          show bioequivalence if the alternative methods are  
16          expected to detect a significant difference between  
17          the drug and the listed drug in safety and thera-  
18          peutic effect.”.

19          (b) EFFECT OF AMENDMENT.—The amendment  
20          made by subsection (a) does not alter the standards for  
21          approval of drugs under section 505(j) of the Federal  
22          Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

23       **SEC. 5. REMEDIES FOR INFRINGEMENT.**

24          Section 287 of title 35, United States Code, is  
25          amended by adding at the end the following:

1       “(d) CONSIDERATION.—In making a determination  
 2 with respect to remedy brought for infringement of a pat-  
 3 ent that claims a drug or a method or using a drug, the  
 4 court shall consider whether information on the patent  
 5 was filed as required under 21 U.S.C. 355 (b) or (c), and,  
 6 if such information was required to be filed but was not,  
 7 the court may refuse to award treble damages under sec-  
 8 tion 284.”.

9   **SEC. 6. CONFORMING AMENDMENTS.**

10       Section 505A of the Federal Food, Drug, and Cos-  
 11 metic Act (21 U.S.C. 355a) is amended—

12               (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i),  
 13       by striking “(j)(5)(D)(ii)” each place it appears and  
 14       inserting “(j)(5)(F)(ii)”;

15               (2) in subsections (b)(1)(A)(ii) and  
 16       (c)(1)(A)(ii), by striking “(j)(5)(D)” each place it  
 17       appears and inserting “(j)(5)(F)”;

18               (3) in subsections (e) and (l), by striking  
 19       “505(j)(5)(D)” each place it appears and inserting  
 20       “505(j)(5)(F)”.

○